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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,358	08/25/2003	Charles Larry Bisgaier	5790-C1	2219

7590 12/02/2005

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,358	BISGAIER ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application has recently been transferred to the undersigned examiner.

This Office action is in reply to applicant's response, filed on 12/20/2004. Claims 1 and 4-5 are presently pending in this application and they are examined herein.

At the outset, it is suggested that applicant amend the first line of the specification to recite the 371 continuation data and claim of benefit of 60/069,432.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth (US 5,273,995) in view of Lee et al. (US 5,489,611) Hunninghake et al., Wanner et al. and Medline abstract 96306618.

Roth explicitly discloses atorvastatin calcium, i.e. Lipitor as a HMG-CoA reductase inhibitor (column 1; Example 10, columns 14-16; claim 6). Treatment of humans suffering from hypercholesterolemia is taught (column 2, lines 48-53). Use as hypolipidemic or hypocholesterolemic agents is disclosed (column 9, lines 14-15). Combined use with other active therapeutic agents is taught (column 9, lines 28-29).

Roth does not expressly disclose a pharmaceutical composition consisting of Lipitor + retinoid Lp(a) inhibitor + carrier.

Lee et al. disclose Lp(a) lowering retinoids such as those recited in applicant's claims 4-5. See Lee's claims 1-11.

Hunninghake et al. disclose a different statin drug, pravastatin, also with HMG-CoA reductase inhibitor activity, does not significantly affect Lp(a) concentrations (abstract; page 578, table and text below). Wanner et al. similarly disclose a different statin drug, simvastatin, also with HMG-CoA reductase inhibitor activity, does not affect Lp(a) concentrations (abstract; pp. 141-143). Medline abstract 96306618 similarly disclose that the use of a different statin drug, fluvastatin, had no short term effect on Lp(a) levels.

It is without question that the ordinary skilled artisan would have known, before the earliest effective filing date of this application, that elevated levels of Lp(a) represented a risk factor for cardiovascular disease[1]. Further, there was sufficient evidence that numerous statin drugs with HMG CoA reductase inhibitor activity were not so good in reducing Lp(a) levels. Therefore, the ordinary skilled artisan in this field would have been quite motivated to enhance the hypocholesterolemic or hypolipidemic actions of Lipitor with Lee's retinoids to lower Lp(a) levels. The combination of two ingredients would have been advantageous because it would have obtained the

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1 See e.g., Lee et al., column 1, lines 36-46; Hunninghake et al., page 574, first two columns of text.

hypocholesterolemic and hypolipidemic activity of Lipitor and the added benefit of Lp(a) lowering activity of retinoids.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

To date, applicant has failed to provide any objective evidence of nonobviousness that may rebut the prima facie case of obviousness established herein.

For these reasons, all claims must be refused.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600